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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-------------|----------------------|---------------------|------------------|
| 10/665,754 | 09/19/2003 | James J. Pagliuca | A31-4000-4 | 8425 |
| 28075 | 7590 | 10/30/2007 | | |
| CROMPTON, SEAGER & TUFTE, LLC | | | EXAMINER | |
| 1221 NICOLLET AVENUE | | | NGUYEN, VI X | |
| SUITE 800 | | | | |
| MINNEAPOLIS, MN 55403-2420 | | | ART UNIT | PAPER NUMBER |
| | | | 3734 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 10/30/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/665,754

Applicant(s)

PAGLIUCA ET AL.

Examiner

Victor X. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Oath/Declaration

1. It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56. Specifically, the oaths/declarations do not have the correct statement with respect to the duty to disclose. The correct statement should read "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,3-5, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhu et al. (5,577,993).

Zhu et al disclose in figures. 2, 4 and 6, a surgical tool 20 for use in expanding a tubular structure as recited in claims 1,4 including: a first leg 54 has a first end 51a, a second leg 54 has a second end 51b, where the first and the second end is moveable away from each other at best seen in fig. 5, and where the tool further includes an actuator 55 which is able to move the first

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and the second legs away from each other (fig. 4). Regarding the intended use” a surgical tool *for use in expanding a tubular structure*, the tubular structure having an inner surface defining a passage through the tubular structure *for receiving surgical instruments*, said first and second ends *being moveable away from each other to apply a radially outwardly directed force to the inner surface of the tubular structure* and cause expansion of the tubular structure *to increase a cross-sectional area of the passage along a portion of the passage*; The statement of intended use and other functional statements have been carefully considered but are deemed not to impose any structure limitations on the claims distinguishable over Zhu reference which is capable of being used as claimed if one desires to do so. Furthermore, the actuator 55 at best seen in fig. 7 definitely is able to move axially (the axially movement occurs along the arrow pointed direction in fig. 7) which moves the first and the second legs away from each other (legs 54 do have flared end portions along the tissue layers 27).

As to claim 3, Zhu et al disclose a first and second handles (56), where the handles move toward each other to move the first and second legs (54) away from each other (fig.5).

As to claims 5 and 7, Zhu et al disclose a member or a depth limiter (element 64 is considered a member or a depth limiter, see col. 9, lines 14-18) which is able for limiting the depth as the surgical tool extends into the passage in the tubular structure or is able to limit the distance of the legs move away from each other.

As to claim 9, it noted that fig. 2 of Zhu clearly defined element 56 as first and second handles *being movable toward each other to pivot said first and second legs relative to each other and move said first and second ends away from each other* (a functional limitation): Thus, a reference needs not show the structure of the recitation in order to meet the claim language but

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rather the reference needs only be capable of being used with such structure. Accordingly, the reference is considered to read on the claimed limitation of the claimed noted.

3. Claims 10-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Makower et al. (5,683,349).

Makower et al disclose in figures. 1, 7, a surgical tool 10 for use in expanding a tubular structure as recited in claims 10-12, including: an elongate member 11, first and second handles at 34 is able to move radially toward and away from each other, first and second legs at 15 connect to the elongate member, the first and second legs are engageable with the inner surface of the tubular structure, and where the first and second legs are moveable away from each other to apply a radially outwardly directed force to the inner surface of the tubular structure, where an actuator 35 is able to move longitudinally to move the first and second legs 15 away from each other(see col. 6, lines 21-27). Regarding the intended use" a surgical tool *for use in expanding a tubular structure*, the tubular structure having an inner surface defining a passage through the tubular structure *for receiving surgical instruments*, said first and second ends *being moveable away from each other to apply a radially outwardly directed force to the inner surface of the tubular structure* and cause expansion of the tubular structure *to increase a cross-sectional area of the passage along a portion of the passage*; The statement of intended use and other functional statements have been carefully considered but are deemed not to impose any structure limitations on the claims distinguishable over Makower reference which is capable of being used as claimed if one desires to do so. Note that the actuator of Makower is positioned inside the elongate member see fig. 7.

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4. Claims 10-13,16-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Sherts (5,728,113).

Sherts discloses in figures. 1, 3, a surgical tool 10 for use in expanding a tubular structure as recited in the above listed claims, including: an elongate member 22, first and second handles at 30 is able to move radially toward and away from each other, first 16 and second legs at 18 connect to the elongate member, the first and second legs are engageable with the inner surface of the tubular structure, and where the first and second legs are moveable away from each other to apply a radially outwardly directed force to the inner surface of the tubular structure, where an actuator 38 is able to move longitudinally to move the first and second legs 16,18 away from each other(see col. 6, lines 21-27) . Furthermore, a spring 58 disposes around the actuator as recited in claim 13. Regarding the intended use” a surgical tool *for use in expanding a tubular structure*, the tubular structure having an inner surface defining a passage through the tubular structure *for receiving surgical instruments*, said first and second ends *being moveable away from each other to apply a radially outwardly directed force to the inner surface of the tubular structure* and cause expansion of the tubular structure *to increase a cross-sectional area of the passage along a portion of the passage*; The statement of intended use and other functional statements have been carefully considered but are deemed not to impose any structure limitations on the claims distinguishable over Sherts reference which is capable of being used as claimed if one desires to do so. As to claims 16-20, Sherts discloses a handle 30 pivotally connected to a first end of a shaft at 22, the handle is able to move between a first expanded configuration and a second contracted configuration, first jaw 16, second jaws 18 pivotally connected to a second end of the shaft at 24, and where the contracting the handle 30 would cause the expansion of the

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first and the second jaws, and where the device further has an actuator 38 which is able to move longitudinally along the shaft to move the first and second jaws away from each other, and where the device further has a spring 58 disposed on the actuator, where the handle includes first and second handle member occur at either side of element 30 in fig. 1a extending radially from the shaft.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu et al (5,577,993).

Regarding claims 6 and 8, Zhu discloses the invention substantially as claimed. Zhu is silent that the device further comprises a depth limiter or a member includes a plurality of positions along the surgical tool to define a plurality of depths or distances that the tool extends into the passage. Instead, Zhu indicates that the device has a stop device 64 which provides an effective impediment to excessive travel and penetration of the trocar 40 (see col. 9, lines 13-17)

At the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to modify Zhu's device with a depth limiter or a member includes a plurality of positions along the surgical tool to define a plurality of depths or distances because Applicant has not disclosed that a depth limiter or a member includes a plurality of positions along the surgical tool to define a plurality of depths or distances provides an

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advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Zhu device, and applicant's invention, to perform equally well with either the device taught by Zhu because both device would perform the same function of providing additional safety and control to the instrument during surgical procedures.

Therefore, it would have been obvious to modify Zhu to obtain the invention as specified in the above claims because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Zhu.

- Claims 14 and 15 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Sherts (5,728,113) in view of Gerrone (5,312,351). Shert discloses the invention substantially as claimed. Shert is silent regarding a depth limiter includes a plurality of positions along the surgical tool.

Gerrone discloses such a depth limiter includes a plurality of positions along the surgical tool (see fig. 7d).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Sherts by making the device has a depth limiter includes a plurality of positions along the surgical tool as taught by Gerrone to allow prediction result of adding an additional safety and control to the instrument.

Response to Arguments

6. Applicant's arguments filed 8/13/2007 have been fully considered but they are not persuasive. The applicant argues that Zhu reference fails to teach an actuator configured to move axially to move first and second legs away from each other. It is noted that the actuator 55

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at best seen in fig. 7 definitely is able to move axially (the axially movement occurs along the arrow pointed direction in fig. 7) which moves the first and the second legs away from each other (legs 54 do have flared end portions along the tissue layers 27). Regarding to new claims 10 and 16, applicant is asked to please refer to the modified prior art rejections above where examiner addresses applicant's concerns regarding the new limitations.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victor X Nguyen
Examiner
Art Unit 3734



VN

10/26/2007



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER